CALIFORNIA GONORRHEA TREATMENT GUIDELINES REVISED JUNE 25, 2003

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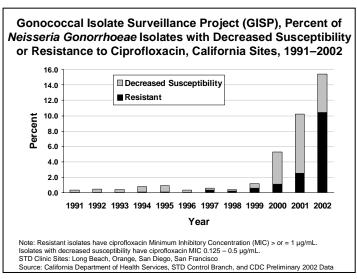
California Department of Health Services Sexually Transmitted Diseases (STD) Control Branch REVISED June 25, 2003

National Gonorrhea Treatment Guidelines

STD treatment guidelines from the Centers for Disease Control and Prevention (CDC) include fluoroquinolones (ciprofloxacin, levofloxacin, and ofloxacin) as first-line therapy for uncomplicated gonococcal infections. However, fluoroquinolones are no longer recommended for the treatment of gonorrhea in areas where fluoroquinolone resistance is prevalent. These areas have included Asia and the Pacific, including Hawaii. Recently, California has been added to the list of areas where fluoroquinolones should not be used as a first line therapy to treat gonorrhea. The CDC STD Treatment Guidelines 2002 can be viewed at: www.cdc.gov/std.

Increasing Fluoroquinolone Resistance in California

Antimicrobial resistance surveillance in California has demonstrated a prevalence of ciprofloxacin-resistant gonorrhea of more than 10% in 2002. Prior to this time period, the level of ciprofloxacin resistance was low (0.2% in 1998, 0.6% in 1999, 1.1% in 2000, 2.5% in 2001), according to data from the national Gonococcal Isolate Surveillance Project (GISP), which provides antibiotic susceptibility testing on gonococcal isolates from male patients with urethral infections seen (the first 25 each month) in sentinel STD clinics. The GISP surveillance system includes four sites in California: San Francisco, Orange County, Long Beach, and San Diego, all of which have experienced a similar increase in cases.



California Gonorrhea Treatment Guidelines

The original release of California Gonorrhea Treatment Guidelines was May 24, 2002. These guidelines were published in the July 2002 issue of the Medical Board of California Action Report. The recommendations are now being revised in light of recent developments in the manufacturing and distribution of medications named in the original release. Specifically, cefixime, the only oral cephalosporin listed as first-line treatment in California, is no longer available through its U.S. distributor and there is currently no other pharmaceutical company manufacturing or distributing cefixime tablets in the United States.

In response to this increase in fluoroquinolone-resistant gonorrhea in California and the unavailability of cefixime, the California Department of Health Services STD Control Branch and the California STD Controllers Association issue the following revised recommendations based on the data available. Factors considered in making these recommendations included efficacy (see table on page 6), cost, side effects, and the potential for emerging resistance. For more information on oral alternatives to cefixime, please go to http://www.cdc.gov/std/treatment/Cefixime.htm.

GONORRHEA TREATMENT RECOMMENDATIONS

- 1. Avoid the use of fluoroquinolones (ciprofloxacin, ofloxacin, and levofloxacin) to treat gonorrhea in California.
- 2. The antibiotics of choice to treat uncomplicated gonococcal infections of the cervix, urethra, and rectum include:
 - Ceftriaxone 125 mg intramuscularly in a single dose;
 OR
 - Cefixime 400 mg orally in a single dose.1

If available.		

- 3. Alternative antibiotic regimens for the treatment of uncomplicated gonococcal infections of the cervix, urethra, and rectum include:
 - ◆ Single-dose injectable cephalosporins: Ceftizoxime 500 mg intramuscularly, Cefoxitin 2 g intramuscularly with Probenecid 1 g orally, or Cefotaxime 500 mg intramuscularly;

OR

• **Spectinomycin** 2 g intramuscularly in a single dose;²

OR

• Azithromycin 2 g orally in a single dose;

OR

◆ Cefpodoxime 400 mg orally in a single dose (some experts use the Federal Drug Administration (FDA)-approved 200 mg dose of Cefpodoxime to treat uncomplicated urogenital infections);

- ◆ Cefuroxime axetil 1 g orally in a single dose.
- 4. The antibiotics of choice to treat gonococcal infections of the pharynx include:
 - ◆ **Ceftriaxone** 125 mg intramuscularly in a single dose;
 - Azithromycin 2 g orally in a single dose.
- 5. For patients with significant anaphylaxis-type (IgE-mediated) allergies to penicillin, where the use of cephalosporins is a concern, or patients with allergies to cephalosporins:
 - Spectinomycin 2 g intramuscularly in a single dose;²

OR

Azithromycin 2 g orally in a single dose;

OR

 A fluoroquinolone (ciprofloxacin, ofloxacin, or levofloxacin) with a test-of-cure.

² Some programs have had difficulty obtaining spectinomycin because the local distributor is unaware that the drug is now available. To obtain spectinomycin, contact Wendy Johnson, Pharmacia Corporation, at (800) 976-7741, extension 30110; fax (800) 852-6421.

PELVIC INFLAMMATORY DISEASE TREATMENT RECOMMENDATIONS

For the treatment of pelvic inflammatory disease (PID), CDC guidelines should be followed. However, if the gonorrhea test is positive in a patient receiving a fluoroquinolone regimen, a test-of-cure should be performed.

CHLAMYDIA CO-TREATMENT RECOMMENDATIONS

Co-treatment of chlamydia in patients with gonorrhea is still recommended unless chlamydia infection has been ruled out using sensitive test technology (e.g., nucleic acid amplification test (NAAT)), or azithromycin 2 grams has been used to treat gonorrhea. Recommended antibiotics for the treatment of chlamydial infection include:

- Azithromycin 1 g orally in a single dose;
 OR
- **Doxycycline** 100 mg orally twice a day for seven days.

TEST-OF-CURE INDICATIONS

Obtaining a test-of-cure is important whenever fluoroquinolones are used or when treatment failure is suspected. If clinicians encounter a treatment failure after any of the gonorrhea treatment regimens listed above, in the absence of re-exposure, they need to take whatever steps are necessary to culture the organism. Gonococcal isolates need to be sent to CDC via the local and state public health laboratory routing.

Question or concerns regarding these recommendations should be addressed to:

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Phone: (510) 540-2657 Email: Gbolan@dhs.ca.gov

Efficacy of Oral Alternatives in Treating Urogenital and Pharyngeal Gonococcal Infections

		Efficacy					
Drug	Dose		genital ection	Pharyngeal Infection		Cost*	Limitations
-		Cure		Cure			
		Rate (%)	95% CI	Rate (%)	95% CI	per dose	
Cefuroxime axetil (Ceftin)	1 g	96.2	94.8-97.5	56.9	43.3-70.5	\$15	Cure rate for pharyngeal GC is unacceptably low.
Cefpodoxime proxetil (Vantin)	200 mg	96.5	94.3-98.5	78.9	54.4-94.0	\$5	Clinical trials on pharyngeal GC included 19 males.
Cefpodoxime proxetil (Vantin)	400 mg	100.0	69.1-100	no publ	ished data	\$10	Clinical trial on urogenital GC included 10 patients.
Ceftibuten (Cedax)	400 mg	98.2	93.6-99.8	no publ	ished data	\$10	Clinical trial on urogenital GC included men only.
Cefdinir (Omnicef)	300-600 mg	no publ	ished data	no publ	ished data	\$5-10	In vitro data only.
Azithromycin (Zithromax)	2 g	99.2	97.2-99.9	100	82.3-100	\$50	High frequency of gastrointestinal side effects.

^{*} Cost based on average wholesale price; actual cost depends on volume, packaging and formulation.